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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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AMERICAN INFERTILITY OF NEW YORK, P.C.,

Civil Action No.

Plaintiff,

**COMPLAINT**

-against-

**JURY TRIAL DEMANDED**

DEEP BLUE HEALTH NEW ZEALAND LTD.,

Defendant.

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**AMERICAN INFERTILITY OF NEW YORK, P.C.'S  
COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff American Infertility of New York, P.C. (American Infertility), by its attorneys,  
La Reddola, Lester & Associates, LLP, for its complaint against defendant Deep Blue Health  
New Zealand Ltd. (Deep Blue Health), alleges:

**The Parties**

1. American Infertility is a New York professional corporation having a place of  
business at 21 East 69<sup>th</sup> Street, New York, New York 10021.

2. Upon information and belief, defendant Deep Blue Health is a New Zealand  
corporation conducting business in the United States and having a place of business at 36C  
Apollo Drive, Mairangi Bay, North Shore 0632, Auckland, New Zealand.

### **Jurisdiction and Venue**

3. This Court has subject matter jurisdiction over this claim pursuant to 28 U.S.C. §§ 1331 and 1338 because this action arises under the United States patent laws, 35 U.S.C. § 101, *et seq.*

4. Upon information and belief, Deep Blue Health is subject to this Court's personal jurisdiction because it regularly conducts business and/or solicits business, engages in other persistent course of conduct and/or derives substantial revenue from goods and/or services sold to persons and/or entities in the State of New York.

5. Upon information and belief, Deep Blue Health directly infringed, continues to directly infringe, induced others to infringe, continues to induce others to infringe, contributed to infringement and continues to contribute to infringement of U.S. Patent No. 8,067,400 (the '400 patent), by manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising, selling or otherwise making available, within the State of New York and elsewhere throughout the United States, products, including but not limited to DHEA 25mg (the Infringing Product), that contains dehydroepiandrosterone (DHEA) and are administered in accordance with the limitations of at least one claim of the '400 patent.

6. Upon information and belief, Deep Blue Health is subject to this Court's personal jurisdiction in accordance with due process and/or the New York long arm statute because it is conducting substantial business in the State of New York. Deep Blue Health engaged in, and continues to engage in, manufacturing, promoting, marketing, having made, using, importing, offering for sale, advertising and/or selling of goods and products, including the Infringing

Product, in the State of New York and are administered in accordance with the limitations of at least one of the claims of the '400 patent.

7. Deep Blue Health has an interactive website on which it markets, advertises, sells and/or offers for sale the Infringing Product to be administered in accordance with the limitations of at least one of the claims of the '400 patent, which website is used, and/or accessible, in the State of New York.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400. Deep Blue Health is subject to personal jurisdiction in this judicial district in accordance with due process and/or the New York long arm statute. Deep Blue Health engaged in, and continues to engage in, the manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising and/or selling goods and products, including the Infringing Product, in this judicial district and are administered in accordance with the limitations of at least one of the claims of the '400 patent. Therefore, the complained of acts of patent infringement occurred, and continue to occur, within this judicial district.

9. Upon information and belief, Deep Blue Health induced, and continues to induce, infringement of the '400 patent by manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising and/or selling goods and products, including the Infringing Product in this judicial district, to be administered in accordance with the limitations of at least one of the claims of the '400 patent.

### **The Patent-in-Suit**

10. On November 29, 2011, the U.S. Patent and Trademark Office duly and validly issued the '400 patent, entitled "Androgen Treatment in Females," naming Norbert Gleicher,

David H. Barad and Dwyn V. Harben as inventors and American Infertility as assignee. A copy of the '400 patent is attached as Exhibit 1.

11. The '400 patent is a continuation-in-part of application no. 10/973,192, filed on October 26, 2004, now abandoned, and a continuation-in-part of application no. 11/269,310, filed on November 8, 2005, now U.S. Patent No. 7,615,544, and a continuation-in-part of application no. 11/680,973, filed on March 1, 2007, now abandoned.

12. The '400 patent is generally directed to a method for improving the quality of embryos, increasing pregnancy rates, and reducing miscarriage rates by administering an androgen, such as DHEA, for at least two months.

13. American Infertility is the assignee and owner of all right, title and interest in and to the '400 patent, including the right to assert all causes of action arising under said patent and the right to seek and recover remedies for infringement of the '400 patent.

**FIRST CLAIM**  
**(Patent Infringement)**

14. American Infertility repeats and realleges each and every allegation contained in paragraphs 1 to 13 as though fully set forth herein.

15. American Infertility owned the '400 patent throughout the period of Deep Blue Health's infringing acts and still owns the '400 patent.

16. At all relevant times herein, the '400 patent is a valid and enforceable patent.

17. Deep Blue Health directly infringed, continues to directly infringe, literally and/or under the doctrine of equivalents, induced others to infringe, continues to induce others to infringe, contributed to infringement and continues to contribute to infringement, within this judicial district and elsewhere throughout the United States, at least one of the claims of the '400

patent, by manufacturing, promoting, marketing, making, having made, using, importing, offering for sale, advertising, selling or otherwise making available the Infringing Product to be administered in accordance with the limitations of these claims without license, permission and/or authorization from American Infertility.

18. Upon information and belief, Deep Blue Health was aware of the '400 patent.

19. Claim 1 of the '400 patent is a "method of decreasing aneuploidy rates in human embryos comprising administering androgen to a female for at least two months."

20. Claim 3 of the '400 patent is a "method according to claim 1, wherein said androgen is dehydroepiandrosterone [DHEA]."

21. Claim 4 of the '400 patent is a "method according to claim 3, wherein said dehydroepiandrosterone administration comprises between 50 and 100 mg per day of said dehydroepiandrosterone."

22. Claim 6 of the '400 patent is for a "method of decreasing time to pregnancy and increasing pregnancy rates in females comprising administering an androgen for at least two months."

23. Deep Blue Health promotional material for the Infringing Product refers to unspecified research which shows that 25-50 mg daily dosages of DHEA is effective to support female fertility and to aid hormonal balance. A screen shot of the Deep Blue Health website for the Infringing Product that makes this claim is attached as Exhibit 2.

24. Deep Blue Health's website states that to support female fertility women should take one or two 25 mg capsules of DHEA daily. (*See* Exhibit 2).

25. Deep Blue Health only offers for sale and sells the Infringing Product in a 60 day (two month) supply through that website. Deep Blue Health's product material and website page

display how to order the 60 day supply of the Infringing Product (25 mg per capsule and 1-2 capsules per day). (*See* Exhibit 2). There are no other apparent amounts that can be ordered from Deep Blue Health. Clearly, Deep Blue Health is aware of the ‘400 patent, and its limitations, but intentionally sells a 60 day supply of the Infringing Product.

26. Deep Blue Health’s promotion, offer of sale, and/or sale of 25 mg daily dosages and a 60 day supply of the Infringing Product, for the purposes set forth therein, is administered, or to be administered, in accordance with the limitations of at least claim 6 of the ‘400 patent.

27. By various letters and email correspondence since February 14, 2017, Cobra Consulting Group, LLC on behalf of American Infertility requested that Deep Blue Health provide it with information regarding Deep Blue Health’s DHEA product sales, marketing, representations and the administration and prescription of DHEA.

28. In a February 14, 2017 email, Deep Blue Health, by its Director Tony Lawton responded that Deep Blue Health was not selling or distributing the DHEA 25mg product in the United States. However, despite the correspondence, Deep Blue Health was selling, and continues to offer for sale its DHEA 25mg product in the United States, despite assurances otherwise. Deep Blue Health did not provide any of the information requested by American Infertility.

29. To date, Deep Blue Health continues its infringing activities.

30. Upon information and belief, Deep Blue Health took active and deliberate steps to induce infringement of the ‘400 patent by advertising and instructing others to purchase, use and/or administer the infringing product in a manner that infringes the ‘400 patent, including showing and directing consumers how to purchase, use and/or administer the Infringing Product on Deep Blue Health’s promotional literature, brochures and/or on its website.

31. Specifically, the product material and Deep Blue Health's website at <https://www.Deep Blue Health.com> as shown in Exhibits 2-4 instruct customers to administer the Infringing Product, DHEA 25mg, in dosages and for purposes and/or effects that are covered by at least one of the claims of the '400 patent. And Deep Blue Health offers for sale and/or sells the Infringing Product only in a quantity for a two months' supply.

32. Upon information and belief, Deep Blue Health knew or should have known that its actions infringe, and would induce infringement of, the '400 patent.

33. Deep Blue Health is willfully and intentionally infringing the '400 patent.

34. Deep Blue Health's unlawful acts of infringement as described herein constitute a violation of 35 U.S.C § 271(a) and/or 35 U.S.C § 271(b).

35. As a direct and proximate consequence of Deep Blue Health's direct and/or inducement of infringement of the '400 patent, American Infertility suffered, and continues to suffer, irreparable injury and monetary damages pursuant to 36 U.S.C §§ 281, 283, 284, 285 and 287.

36. Upon information and belief, Deep Blue Health's direct infringement and/or inducement of infringement of the '400 patent will continue unless enjoined by this Court.

37. By reason of the foregoing, American Infertility seeks damages and a trebling thereof and preliminary and permanent injunctions enjoining Deep Blue Health from committing further acts of infringement of the '400 patent.

**Jury Demand**

38. American Infertility hereby demands a trial by jury on all issues so triable.

**Reservation of Rights**

39. The above allegations and claims are based upon information known to American Infertility, and/or upon American Infertility's information and belief at this time. American Infertility's discovery and investigation in this action is continuing and American Infertility reserves its right to supplement and/or amend such allegations and claims.

**Demand for Relief**

WHEREFORE, American Infertility demands judgment and an order:

- A. Adjudicating that Deep Blue Health infringed the '400 patent;
- B. Preliminarily and permanently enjoining Deep Blue Health and its respective officers, directors, agents, affiliates, subsidiaries, parents, employees, and those persons and entities in active concert therewith, from committing further acts of direct infringement and/or inducement of infringement of the '400 patent;
- C. Awarding American Infertility damages for the Deep Blue Health's infringement of the '400 patent pursuant to 35 U.S.C. § 284;
- D. Awarding American Infertility treble damages for Deep Blue Health's willful and intentional infringement of the '400 patent pursuant to 35 U.S.C. § 284;
- E. Awarding American Infertility pre-judgment and post-judgment interest as applicable by law;
- F. Awarding American Infertility its costs incurred in this action;
- G. Declaring this case "exceptional" under 35 U.S.C. § 285, and awarding American Infertility its attorneys' fees in this matter;



H. Requiring Deep Blue Health to render an accounting to American Infertility for Deep Blue Health's profits or the value of the business opportunities received from the foregoing acts of patent infringement; and

I. Granting American Infertility such other and further relief as this Court deems just and proper.

Dated: Garden City, New York  
July 26, 2017

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ASSOCIATES, LLP

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